

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
William G. Dennis

Confirmation No.: 7534

Application No.: 10/702,189

Technology Center: 3700

Filed: November 5, 2003

Group Art Unit: 3731

For: OCCLUSION CLIP

Examiner: T. V. Nguyen

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Appellant submits this brief in support of his appeal initiated by the Notice of Appeal filed on August 25, 2008. Appellant filed a Pre-Appeal Brief Request for Review at the same time, the decision for which was mailed November 7, 2008. The extendible deadline for filing the Appeal Brief is therefore December 7, 2008, which is automatically extended to Monday, December 8, 2008. The fee required under 37 C.F.R. § 41.20(b)(2) has been paid electronically. The Commissioner is authorized to charge any other fee necessitated by the filing of this paper to Deposit Account No. 06-1448, ref. MPD-002.01.

(1) Real Party in Interest

The real party in interest in this appeal is Microline PENTAX, Inc., a Delaware Corporation having its principal place of business at 800 Cummings Center, Suite 157-X, Beverly, Massachusetts 01915. Microline PENTAX, Inc. is the Assignee of the entire

right, title, and interest in the present application by virtue of the following chain of title from the inventor to it:

1. From: DENNIS, WILLIAM G. To: DAISY MEDICAL CORPORATION

The document was recorded in the United States Patent and Trademark Office at Reel 014959, Frame 0371.

2. From: DAISY MEDICAL CORPORATION To: GYRX LLC

The document was recorded in the United States Patent and Trademark Office at Reel 014959, Frame 0350 and at Reel 017541, Frame 0723.

3. From: GYRX LLC To: MICROLINE PENTAX, INC.

The document was recorded in the United States Patent and Trademark Office at Reel 017758, Frame 0481.

(2) Related Appeals and Interferences

There are no other appeals or interferences known to Appellant, the Assignee, or to the Attorneys/Agents of record, which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) Status of Claims

The application has a total of seventy claims. Of these, claims 1-15 and 60-70 are pending and claims 16-59 are cancelled. Claims 1-15 and 60-70 stand finally rejected and are on appeal.

(4) Status of Amendments

No amendments were filed subsequent to final rejection.

(5) Summary of Claimed Subject Matter

Independent claim 1 recites an occlusion clip (Specification, p. 3 line 4; p. 10 line 22; Fig. 3 reference number 40). The occlusion clip includes an occlusion portion (Specification, p. 11 line 1; Fig. 3 reference number 47), a spring portion (Specification, p. 10 line 22; Fig. 3 reference number 46), and a clip guide portion (Specification, p. 10 line 23; Fig. 3 reference number 48). The occlusion portion has an upper single element occlusion member (Specification, p. 10 lines 25-26; Fig. 3 reference number 42) having proximal and distal upper member ends (specification, p. 3 line 6) and a lower single element occlusion member (Specification, p. 10 lines 26-27; Fig. 3 reference number 43) having proximal and distal lower member ends (Specification, p. 3 line 7). The lower single element occlusion member and the upper single element occlusion member combine to define an occlusion member plane (Specification, p. 3 lines 7-9; p. 10 lines 15-16; Fig. 7, plane defined by reference numbers L and P1). The spring portion includes a torsion spring (Specification, p. 10 line 27; Fig. 3 reference number 41) that connects the proximal upper member end to the proximal lower member end (Specification, p. 10 lines 25-27). The torsion spring has a spring height dimension in the occlusion member plane perpendicular to the upper and lower single occlusion members (Specification, p. 3 lines 11-12; Fig. 3 reference number H_C). The torsion spring is adapted to bias the upper and lower single element occlusion members toward a closed position wherein the upper single element occlusion member is in force contact with the lower single element occlusion member (Specification, p. 3 lines 12-15; p. 6 lines 5-6). The clip guide portion has an upper clip guide extending from the distal upper member end (Specification, p. 11 lines 6-

7; Fig. 3 reference number 44) and a lower clip guide extending from the distal lower member end (Specification, p. 11 lines 6-7; Fig. 3 reference number 45). The occlusion portion and the spring portion are formed from wire having a wire width (Specification, p. 6 lines 19-20; p. 11 lines 4-5; Fig. 4 reference number W_O), and the occlusion portion and the spring portion are each no wider, perpendicular to the occlusion member plane, than the wire width (Specification, p. 6 lines 20-22; p. 11 lines 4-5). The clip guide portion is wider than the wire width (Specification, p. 7 line 12; Fig. 4 reference number W_O).

Independent claim 62 recites an occlusion clip (Specification, p. 3 line 4; p. 10 line 22; Fig. 3 reference number 40). The clip comprises a single continuous wire segment (Specification, p. 7 lines 13-14) having a wire width (Specification, p. 6 lines 19-20; p. 11 lines 4-5; Fig. 4 reference number W_O) and first and second wire ends (Specification, p. 11 line 6; Fig. 3 reference numbers 44, 45). The wire segment is so formed as to have a wire loop (Specification, p. 10 line 27; Fig. 3 reference number 41), an upper leg extending from an upper portion of the wire loop to the first wire end (Specification, p. 10 lines 25-26; Fig. 3 reference number 42), and a lower leg extending from a lower portion of the wire loop to the second wire end (Specification, p. 10 lines 26-27; Fig. 3 reference number 43). All bends in the wire segment to form the wire loop and the upper and lower legs occur in only one plane (Specification, p. 7 line 11; Specification, p. 10 lines 27-29). The upper portion of the wire loop so overlies the lower portion of the wire loop that the wire loop as a whole has a width no greater than the wire width (Specification, p. 16 lines 20-21 (“occlusion members 42, 43 . . . lie over and engage one another as shown in FIG. 3”); Fig. 3 reference numbers 42-43; Fig. 4 reference number 42). Each of the upper leg and the

lower leg includes a distal portion, termed a clip guide portion, at the respective first or second wire end (Specification, p. 11 lines 6-7; Fig. 3 reference numbers 44, 45) and a proximal portion, termed an occlusion portion, extending from the wire loop to the respective clip guide portion (Specification, p. 10 lines 25-27; Fig. 3 reference numbers 42, 43). The occlusion portions collectively define an occlusion region of the occlusion clip (Specification, p. 11 line 1; Fig. 3 reference number 47). The occlusion region as a whole has a width no greater than the wire width (Specification, p. 6 lines 19-20; p. 11 lines 4-5; Fig. 4 reference number W_0). The wire loop biases the occlusion clip to a closed position in which the upper leg occlusion portion would contact the lower leg occlusion but for an object intervening between the occlusion portions (Specification, p. 6 lines 4-6; Fig. 8). The bias creates a clamping force between the upper leg occlusion portion and the lower leg occlusion portion, in the closed position, sufficient to occlude a vessel or duct intervening between the occlusion portions (Specification, p. 14 lines 2-3; Fig. 8). Each clip guide portion has a width that is greater than the wire width (Specification, p. 7 line 12; Fig. 4 reference number W_0).

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant submits one ground of rejection for review:

- A. whether the subject matter of claims 1-15 and 60-70 is unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. No. 6,193,732 to Frantzen et al. (“Frantzen”) in view of U.S. Pat. No. 3,797,076 to Watkin (“Watkin”).

(7) Argument

A. Rejection under 35 U.S.C. § 103(a) over Frantzen in view of Watkin.

1. Claims 1, 3-14, 60-62, and 64-70.

The rejected claims are directed to occlusion clips requiring (among other things) that the distal tips (“clip guides”) of a clip be wider than the rest of the clip. The widened clip guides slide up on recessed rails in the jaws of a clip applicator and then snap together when pushed past the rails’ termination (see Figs 15-16 and specification paragraph [0058] of the present application at p. 13 line 25 to p. 14 line 5).

The Examiner acknowledged that the tips of Frantzen’s clips are not taller¹ than the rest of the clip but took the view that such a modification would have been obvious, as evidenced by the wide lips of Watkin’s clothes clip.

However, Frantzen teaches away from such a modification, and hence the claimed invention, because it would render the Frantzen clip unsuitable for its intended purpose.

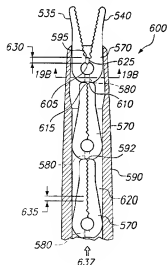


FIG. 19A

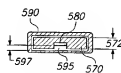
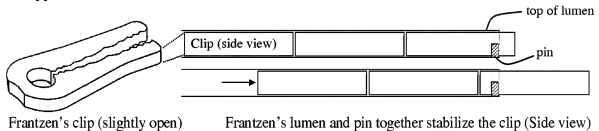


FIG. 19B

Frantzen’s clip and clip applicator are best shown in Figs. 19A-B and described in cols. 17-18. As Frantzen unambiguously states in lines 6-10 of col. 17: “Surgical clip 570 has a sufficiently small clearance within central lumen 620 such that the entire line of clips may be pushed in the direction of

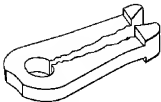
¹ “Widths” as recited in the rejected claims correspond to heights in Frantzen, because Frantzen’s clip arms are illustrated as lying side-by-side, while the claimed clips’ arms overlap one another.

arrow 637 without the clips becoming misaligned or jamming within central lumen 620.” This disclosure means that the height of Frantzen’s clip (when oriented sideways) must so closely match the tube’s height that the clips can’t tilt up or down; otherwise, advancing the clip row would tend to make the clips pitch into the tube walls and buckle with respect to one another. Frantzen prevents the tilting by closely matching the clip dimensions to those of the lumen. The low clearance between his lumen and clip also allows Frantzen to dispense with external guides for the clip, a feature he touts as a significant advantage of his design to improve endoscopic visibility (col. 2, lines 17-19 and 31-32; col. 18, lines 5-8). So as Frantzen’s user advances the clip from the applicator, the lumen’s walls and pin work together to hold the clip steady, even as the clip protrudes almost completely from the applicator:

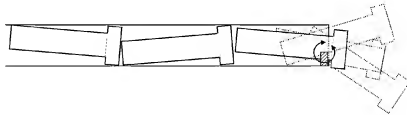


Frantzen’s clips therefore *must be flat*. His flat clips and small-clearance lumen fit hand-in-glove by express design. Yet the Examiner proposes to modify Frantzen’s clip in view of Watkin by making the tips taller than the rest of the clip. Such a modification would be fundamentally at odds with Frantzen’s system because it would destroy the “small clearance” Frantzen expressly calls for and would directly result in tilting, buckling, and wobble, *the very problems that Frantzen expressly seeks to solve*.

A clip so modified would resemble the illustration below, and, as immediately apparent, would undermine Frantzen's design principles.²



Modified clip (slightly open)



Modified clips jam, wobble, and pivot

Because the lumen must accommodate the tall front end, the back end would fit loosely within the applier lumen, and the clips would be free to jiggle. And when the row of clips is pushed from behind, the natural reaction of the clips will be to buckle in order to relieve the compression, thereby pitching up or down and jamming into the lumen wall.

Moreover, once the tall part of the clip has emerged from the free end of Frantzen's clip applier, *nothing holds the narrow clip back-end inside the applier's tall lumen*, except perhaps pin 595. But that pin's grip is insufficient to keep the pin steady in the lumen; even worse, it will act as a pivot point for the narrow clip to wobble within the lumen. Such wobble, of course, needlessly complicates the already challenging task of maneuvering a clip onto a blood vessel during laparoscopic surgery. Even a light bump against an anatomic structure could dislodge a "modified" clip with a springy snap that sends it flying anywhere inside the patient's abdomen.

² The "modified" illustrations are creations of the undersigned attorney prepared for purposes of argument; they do not constitute an admission that such modification is obvious or even realizable from Frantzen's disclosure.

There is no way to fix the problem the Examiner's modification creates without complicating Frantzen's design in just the ways from which Frantzen teaches away, such as by adding jaws or other external stabilizing mechanisms that will impair visibility. For this reason, Frantzen's disclosure teaches away from heightened tips, such as those shown in Watkin, and also away from the claimed clips, because *they simply will not work* in Frantzen's device.

The Examiner's comments in the Advisory Action do not answer or dispel these concerns; even if the proposed modification could somehow improve stability in one axis (though clearly not the "longitudinal axis" the Examiner names, or any other as far as Appellant can tell), it would reduce the overall stability of the clips to the point of uselessness. Moreover, Frantzen already achieves all the stability he deems necessary with his flat clips that fit snugly in the lumen; the Examiner's proposed modification undermines Frantzen's simple design for no purpose and no benefit.

The rejection therefore lacks an essential element required to establish a prima facie case of obviousness: a rationale for combining the references. The Supreme Court of the United States affirmed the need to show a rationale to combine or modify in an obviousness rejection,³ a need the Office acknowledged in formulating its new obviousness examination guidelines.⁴ Appellant has shown that, in fact, Frantzen teaches away from Watkin and the claimed subject matter. Thus, the references themselves actively dissuade one of ordinary skill in the art from making the combination.

³ *KSR Int'l v. Teleflex*, 550 U.S. ___, ___, 82 U.S.P.Q.2d 1385, 1396, slip op. at 14 (US 2007).

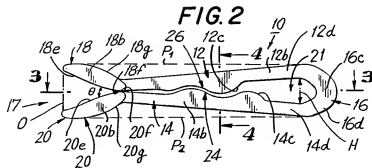
⁴ M.P.E.P. § 2141.

2. Claims 2 and 15.

Claims 2 and 15 require that the upper and lower clip guides include first and second planar members, respectively, such that (a) the first planar member is perpendicular to the occlusion member plane when the occlusions members are in engagement, and (b) the second planar member is parallel to the first planar member when the occlusion members are in engagement.

Franzten does not teach these limitations because he does not disclose clip guides, as acknowledged by the Examiner. But not only does Watkin also fail to teach these limitations, he teaches away from them. Watkin clearly states at col. 3 line 43 that “mouth 17 comprising the lips 18, 20 is open” and at lines 51-55 that:

To achieve the wide-open orientation of the mouth 17, the cam surfaces 18e, 20e meet at an angle θ in the range of approximately 20° to 70° , and desirably approximately 60° , with each surface being 30° away from a horizontal plane, as the clip is viewed in FIG. 2.



Watkin by express design provided a clip with a wide-mouthed opening for his clothing clip to make it easy for a user to mount the clip on an article without first having to pry apart the clip arms (col. 5, lines 25-30; col. 1, lines 53-55). His lips are set at an angle to one another so that an article thrust between them forces the arms apart.

Consequently, neither can a lip be perpendicular to the occlusion member plane (a vertical plane dividing the clip in right and left halves; see plane L-P1 in Appellant's Fig. 7) nor parallel to the other lip when arms 12, 14 are engaged (or indeed in any other orientation). Watkin thus dissuades the reader from its combination with Frantzen to reach the subject matter of claims 2 and 15.

3. Claim 63.

Claim 63 requires that each clip guide portion taper in height distally toward the respective first or second wire end. But Watkin specifically requires that lips increase in height distally so that the distal end of the clip regains the same height as the proximal end of the clip. As shown in Fig. 2 and explained at col. 4, lines 24-28, Watkin's plane P₁ joins the outermost edge of lip 18 to the edge of arm 12, and parallel plane P₂ joins the outermost edge of lip 20 to the edge of arm 14. Arms 12 and 14 taper in height distally, so lips 18 and 20 must enlarge in height distally to restore the height of the proximal end. Watkin emphasizes the importance of this "parallel" configuration to facilitate vertical stacking of this clips in a clip dispenser (col. 4, lines 32-34; Fig. 9).

As shown in Fig. 2, the outermost edges of Watkin's lips 18 and 20 occur at the distal tips. Watkin's lips (likened by the Examiner to the claimed clip guide portions) thus enlarge in height distally toward the ends, exactly the opposite of that claimed. Watkin therefore unambiguously teaches away from the claimed subject matter.

(8) Claims Appendix

See page 13 of this Appeal Brief.

(9) Evidence Appendix

See page 18 of this Appeal Brief.

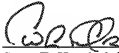
(10) Related Proceedings Appendix

See page 19 of this Appeal Brief.

CONCLUSION

For the reasons given above, Appellant asks that the rejection of claims 1-15 and 60-70 be reversed.

Respectfully submitted,
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(8) Claims Appendix

1. An occlusion clip comprising:
 - an occlusion portion having
 - an upper single element occlusion member having proximal and distal upper member ends;
 - a lower single element occlusion member having proximal and distal lower member ends, the lower single element occlusion member and the upper single element occlusion member combining to define an occlusion member plane;
 - a spring portion having
 - a torsion spring connecting the proximal upper member end to the proximal lower member end, the torsion spring having a spring height dimension in the occlusion member plane perpendicular to the upper and lower single occlusion members and being adapted to bias the upper and lower single element occlusion members toward a closed position wherein the upper single element occlusion member is in force contact with the lower single element occlusion member; and
 - a clip guide portion having
 - an upper clip guide extending from the distal upper member end; and
 - a lower clip guide extending from the distal lower member end;

wherein:

 - the occlusion portion and the spring portion are formed from wire having a wire width, and the occlusion portion and the spring portion are each no wider, perpendicular to the occlusion member plane, than the wire width; and
 - the clip guide portion is wider than the wire width.
2. An occlusion clip according to claim 1, wherein:

the upper clip guide includes a first planar member having a top upper guide surface and an engaging bottom upper guide surface, the first planar member being perpendicular to the occlusion member plane when the upper and lower single occlusion members are in engagement; and
the lower clip guide includes a second planar member having a bottom lower guide surface and an engaging top lower guide surface, the second planar member being parallel to the first planar member when the upper and lower single occlusion members are in engagement.

3. An occlusion clip according to claim 1 wherein the spring height dimension increases as a rotational separation between the single element upper occlusion member and the single element lower occlusion member increases.
4. An occlusion clip according to claim 1 wherein the upper and lower single element occlusion members and the torsion spring are formed from a single continuous wire segment having first and second wire ends.
5. An occlusion clip according to claim 4 wherein the wire segment is formed from titanium and has a diameter in a range from about 10 mils to about 50 mils.
6. An occlusion clip according to claim 4 wherein the wire segment is formed from titanium and has a diameter in a range from about 20 mils to about 40 mils.
7. An occlusion clip according to claim 1 wherein the torsion spring biases the upper and lower single occlusion members to exert an occluding force of at least 0.20 pounds.
8. An occlusion clip according to claim 1 wherein the widths of the occlusion portion and the spring portion are each in a range from about 10 mils to about 50 mils.
9. An occlusion clip according to claim 8 wherein the widths of the occlusion portion and the spring portion are each in a range from about 20 mils to about 40 mils.
10. An occlusion clip according to claim 4,
wherein the wire has a height, and the occlusion portion has a maximum occlusion height dimension in the occlusion member plane that is no greater than twice the wire height.

11. An occlusion clip according to claim 10 wherein the wire segment is formed from titanium and has a diameter in a range from about 10 mils to about 40 mils.
12. An occlusion clip according to claim 10 wherein the wire segment is formed from titanium and has a diameter in a range from about 15 mils to about 30 mils.
13. An occlusion clip according to claim 10 wherein the torsion spring defines a maximum interior height dimension in the occlusion plane when the upper and lower single occlusion members are in engagement, the maximum interior height dimension being less than twice the wire height.
14. An occlusion clip according to claim 10 wherein the torsion spring biases the upper and lower single occlusion members to exert an occluding force of at least 0.20 pounds.
15. An occlusion clip according to claim 10, wherein:
the upper clip guide includes a first planar member having a top upper guide surface and an engaging bottom upper guide surface, the first planar member being perpendicular to the occlusion member plane when the upper and lower single occlusion members are in engagement; and
the lower clip guide includes a second planar member having a bottom lower guide surface and an engaging top lower guide surface, the second planar member being parallel to the first planar member when the upper and lower single occlusion members are in engagement.

Claims 16-59 (Canceled)

60. An occlusion clip according to claim 2, wherein the upper clip guide has a width greater than a width of the upper single occlusion member, and the lower clip guide has a width greater than a width of the lower single occlusion member.
61. An occlusion clip according to claim 15, wherein the upper clip guide has a width greater than a width of the upper single occlusion member, and the lower clip guide has a width greater than a width of the lower single occlusion member.
62. An occlusion clip comprising a single continuous wire segment having a wire width and first and second wire ends and being so formed as to have a wire loop, an

upper leg extending from an upper portion of the wire loop to the first wire end, and a lower leg extending from a lower portion of the wire loop to the second wire end, wherein:

all bends in the wire segment to form the wire loop and the upper and lower legs occur in only one plane;

the upper portion of the wire loop so overlies the lower portion of the wire loop that the wire loop as a whole has a width no greater than the wire width;

each of the upper leg and the lower leg comprises:

a distal portion, termed a clip guide portion, at the respective first or second wire end; and

a proximal portion, termed an occlusion portion, extending from the wire loop to the respective clip guide portion;

the occlusion portions collectively define an occlusion region of the occlusion clip; the occlusion region as a whole has a width no greater than the wire width;

the wire loop biases the occlusion clip to a closed position in which the upper leg occlusion portion would contact the lower leg occlusion but for an object intervening between the occlusion portions;

the bias creates a clamping force between the upper leg occlusion portion and the lower leg occlusion portion, in the closed position, sufficient to occlude a vessel or duct intervening between the occlusion portions; and

each clip guide portion has a width that is greater than the wire width.

63. The occlusion clip of claim 62, wherein each clip guide portion tapers in height distally toward the respective first or second wire end.
64. The occlusion clip of claim 62, wherein the clamping force is at least 0.20 pounds.
65. The occlusion clip of claim 62, wherein the clip has mirror-image symmetry with respect to the plane in which the bends occur.
66. The occlusion clip of claim 62, wherein the clip has mirror-image symmetry with respect to a plane that is perpendicular to the plane in which the bends occur and that divides the clip into upper and lower halves.

- 67. The occlusion clip of claim 66, wherein the clip has mirror-image symmetry with respect to the plane in which the bends occur.
- 68. The occlusion clip of claim 62, wherein the clip is formed from a material comprising titanium.
- 69. The occlusion clip of claim 62, wherein the clip is formed from a titanium alloy.
- 70. The occlusion clip of claim 69, wherein the titanium alloy comprises Ti-6Al-4V ELI.

(9) Evidence Appendix

None.

(10) Related Proceedings Appendix

None.